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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,439	02/08/2001	Antoine Noujaim	107823.178	6671

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EXAMINER
HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
1642	16

DATE MAILED: 04/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/779,439	NOUJAIM, ANTOINE	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communicati n appears n the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 22 and 24 were amended.

2. Claims 1-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made **without** traverse in Paper No. 10.

3. Claims 22-25 are under examination.

4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

5. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

6. The rejection of claims 22-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of arguments and amendments to the claims.

Response to Arguments

7. The rejection of claims 22-25 under 35 U.S.C. 103(a) as being unpatentable over Madiyalakan et al (WO 97/42973, published 11/20/97, IDS #5) and further in view of Goletz et al (U.S. Patent 5,997,869, issued 12/99) is maintained.

The response filed 2/12/03 has been carefully considured but is deemed not to be persuasive. The response states that Madiyalakan et al does not teach or suggest

testing of T cell responses for the purpose of efficacy to continue treatment and Madiyalakan et al does not teach the testing of the T cell response before administration (see page 5 of response). In response to these arguments, Madiyalakan et al clearly teaches generation of a cytotoxic T cell response leads to increased survival in patients injected with the Mab-43.13 (see example 8 and 9). In addition, the rejection is based on a combination of teachings and Goletz et al is supplied for the teachings of testing prior to administration.

The response further states that Goletz et al does not teach treatment with a xenotypic antibody nor does he teach measuring after administration of the antibody and one skill in the art would not be motivated to combine the non-analogous art (see pages 5-6). In response to these arguments, it appears that the response argues the references individually and in response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to non-analogous art, A prior art reference is analogous if the reference is in the field of applicant's endeavor or, if not, the reference is reasonably pertinent to the particular problem with which the inventor was concerned. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In the instant case the reference is pertinent to the invention because the preliminary step can be performed to boost a response (see column 15, lines 40-47).

Thus, it would have been obvious to one skill in the art to determine the CTL response prior to administration because it is routine in the art to perform such a determination of CTL response prior to immunization in order to have a control to determine if an enhanced CTL response was obtained.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

8. The rejection of claims 22-25 under 35 U.S.C. 103(a) as being unpatentable over Madiyalakan et al (U.S. Patent 6,241,985, filed 3/20/98, IDS #5) and further in view of Goletz et al (U.S. Patent 5,997,869, issued 12/99) is maintained.

The response filed 2/12/03 has been carefully considured but is deemed not to be persuasive. The response is essentially as set forth above and in response to these arguments, the response above is applied.

The following are some NEW GROUNDS of rejections

Claim Rejections - 35 USC § 112

9. Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 22 –25 are indefinite for reciting "wherein the T cell response produced to such antigen after administration...relative to the level of the T cell

response produced by the patient prior to the administration" in claim 22 because the exact meaning of the phrase is not clear. Does the T cell response increase or decrease upon administration of the xenotypic antibody?

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Madiyalakan et al (WO 97/42973, published 11/20/97, IDS #5).

The claims recite a method for diagnosing the efficacy of xenotypic antibody-mediated immunotherapy comprising measuring the level of a T helper cell or cytotoxic T cell response produced in a human that has a disease associated with an antigen of the xenotypic antibody, wherein the T cell response produced to such antigen after administration of the antibody relative to the T cell response produced prior to administration is indicative of a favorable diagnosis.

Madiyalakan et al teach administration of a mouse antibody directed to CA125 which is Mab-B43.13 which led to increased in cytotoxic T lymphocytes in human cancer patients (see Examples 2 and 8) and stimulates both a humoral and cellular response and administration of the xenotypic antibody led to an increase in the mean survival of the patients (see example 9). Madiyalakan et al also teach the CA125 antigen fails to be recognized by the immune system (see page 16) and as such there would be no T cell response prior to administration. The claims only recite a T cell response after administration which Madiyalakan et al teaches and if there is no T cell response prior to administration and one after it would be inherent that there was a relative level of change thus the art reads on the claims.

12. Claims 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Madiyalakan et al (U.S. Patent 6,241,985, filed 3/20/98, IDS #5).

The claims have been described supra.

Madiyalakan et al teach administration of a mouse antibody directed to CA125 which is Mab-B43.13 which led to increased in cytotoxic T lymphocytes in human

cancer patients (see Examples 2 and 8) and stimulates both a humoral and cellular response and administration of the xenotypic antibody led to an increase in the mean survival of the patients (see example 9). Madiyalakan et al also teach the CA125 antigen fails to be recognized by the immune system (see col 10, lines 14-16) and as such there would be no T cell response prior to administration. The claims only recite a T cell response after administration which Madiyalakan et al teaches and if there is no T cell response prior to administration and one after it would be inherent that there was a relative level of change thus the art reads on the claims.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of

this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879